

**IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE NORTHERN DISTRICT OF GEORGIA**

ELIZABETH A. LAKEY, et al.,

Plaintiffs,

v.

MENTOR CORPORATION,

Defendant.

Civil Action No. 1:05-CV-0929-TCB

**DEFENDANT MENTOR CORPORATION'S MOTION FOR SUMMARY
JUDGMENT AND MEMORANDUM OF LAW IN SUPPORT**

Plaintiffs Elizabeth Lakey and Gary Lakey (“plaintiffs”) have asserted two – and only two – claims against Mentor Corporation for injuries allegedly related to Ms. Lakey’s saline-filled breast implants: (1) negligence and (2) intentional infliction of emotional distress. (See First Am. Comp., Docket #61). The undisputed facts confirm that both claims fail as a matter of law, for multiple reasons. Summary judgment is appropriate.

As an initial matter, both of plaintiffs’ claims fail because they are premised on two unprovable assertions, i.e., that the Mentor implants at issue were defective and that the implants proximately caused plaintiffs’ alleged injuries. Indeed, the uncontested facts show otherwise. The Mentor implants have an FDA-approved design, were manufactured flawlessly and performed precisely as

anticipated. The implants did not malfunction in any way. And, to the extent plaintiffs actually sustained any alleged injuries, they have proffered no scientific evidence whatsoever (nor could they) to connect those injuries to Mentor's implants. Rather, as plaintiffs' counsel correctly admitted in open court, there is an "analytical gap" and "missing link" in plaintiffs' attempt to connect any injuries to the Mentor implants. (Aug. 1, 2006 Hrg. Transcript at 4-5, Docket #99). Thus, for these two fundamental reasons, plaintiffs' negligence and emotional distress claims fail as a matter of law.

Plaintiffs' claims fail for other reasons, too. For instance, the negligence claim fails also because plaintiffs have submitted no admissible standard-of-care evidence. Rather, the undisputed facts confirm that Mentor, which manufactured and sold an implant with an FDA-approved design, pursuant to FDA good manufacturing practices and accompanied by an FDA-reviewed warning insert, was not negligent in any way. The emotional distress claim fails, as well, because plaintiffs cannot show that Mentor acted "outrageously" or with the requisite intentional or reckless disregard. Thus, for any of these multiple independent reasons, summary judgment should be granted and plaintiffs' claims should be dismissed.

ARGUMENT¹

I. PLAINTIFFS CANNOT PROVE PRODUCT DEFECT OR CAUSATION.

A. The Undisputed Facts Confirm that the Mentor Implants at Issue Were Not Defective.

Both of plaintiffs' claims are founded upon proving that something was wrong with the Mentor implants, i.e., that they were defective. (First Am. Comp., Docket #61, at ¶ 7 ("the implants were defectively designed and/or constructed"); see also ¶¶ 8-9, 15). They are unable to do so here.

Courts around the country routinely grant summary judgment for medical device manufacturers (including Mentor) on defect-based claims where – like here – a plaintiff proffers no evidence that a defect existed in the device at issue. See, e.g., Taylor v. Danek Med., Inc., No. 95-7232, 1998 WL 962062, at *7-*8 (E.D. Pa. Dec. 29, 1998) (granting summary judgment for manufacturer of bone screw

¹ The federal summary judgment standard is well established. Federal Rule of Civil Procedure 56 requires the Court to render summary judgment if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any" show that there is no genuine issue of material fact. Fed. R. Civ. P. 56(c). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims . . ." Celotex Corp. v. Catrett, 477 U.S. 317, 323-24, 106 S.Ct. 2548 (1986). The party seeking summary judgment bears the initial responsibility of demonstrating the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. It is then incumbent on the non-moving party to go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial. Id. at 324.

because plaintiff failed to submit proof of defect), attached as Exhibit 1. See also Barnett v. Mentor H/S, Inc., 133 F. Supp. 2d 507, 511-12 (N.D. Tex. 2001) (granting summary judgment for Mentor on several defect-based claims because the plaintiff had “not presented competent summary judgment evidence to controvert Mentor’s evidence that the implants were not defective”), aff’d, No. 01-10328, 2001 U.S. App. LEXIS 28226 (5th Cir. Dec. 13, 2001); Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 (D. Ariz. 1999) (granting summary judgment for Mentor because plaintiff failed to submit proof of defect), aff’d, No. 00-15279, 2001 U.S. App. LEXIS 17223 (9th Cir. Aug. 1, 2001).

Both of plaintiffs’ claims fail because there is no proof that there was any defect in the Mentor implants. It is undisputed that prior to placing the implants into plaintiff, plaintiff’s physician, Dr. Pound, thoroughly examined and leak-tested the implants and found that they were sterile and free from defects. (SOF ¶ 25). It also is undisputed that, after the implant surgery, Dr. Pound saw plaintiff on at least three occasions and plaintiff reported that she was “happy” and had no complications or complaints about her implants. (SOF ¶ 26). And it is undisputed that, after Dr. Kolb convinced plaintiff to undergo explant surgery, when the implants were removed they were intact; they had not ruptured, leaked, deflated or malfunctioned. (SOF ¶ 31). Nor did the implants contain any “mold” or “debris”

within the implants. Pathology cultures from plaintiff's breast tissue were negative for aerobic or anaerobic microbial growth. (SOF ¶¶ 28-30).

Mentor's uncontroverted affirmative evidence confirms that the implants were not defective. Specifically, the Mentor implants have an FDA-approved design that has been subjected to years of clinical studies and have been determined to be "safe and effective" after undergoing the FDA's most rigorous review process: pre-market approval. (SOF ¶ 2). The implants that plaintiff received underwent exhaustive pre-shipment quality assurance and sterility testing and inspection pursuant to FDA good manufacturing practices and met all requirements. (SOF ¶¶ 9-20, 24). And the implants were accompanied by FDA-reviewed warnings that, according to plaintiffs' own surgeon, adequately reported known inherent risks associated with use of the implants. (SOF ¶¶ 3-8, 65).

Under these undisputed facts, plaintiffs cannot show that the Mentor implants were defective. Without such proof, summary judgment on both of plaintiffs' claims is appropriate.

B. Plaintiffs Cannot Prove Proximate Causation.

Plaintiffs' negligence and emotional distress claims also are founded upon proving that the Mentor implants caused their injuries. (First Am. Comp., Docket #61, at ¶¶ 7-9). But they cannot prove this essential element of their claims, either.

Georgia law requires plaintiffs to prove that Mentor's implants were the proximate cause of their alleged injuries, whether proceeding under a negligence or emotional distress theory. Bradley Ctr., Inc. v. Wessner, 250 Ga. 199, 200 (1982) (causation is essential element of negligence claim); Northside Hosp. v. Ruotanen, 246 Ga. App. 433, 435 (2000) (there must be a causal connection between the wrongful conduct and the emotional distress). Where, like here, a plaintiff alleges complicated medical injuries from exposure to a product, expert medical testimony to a reasonable degree of medical certainty is required to carry a plaintiff's burden of proving causation. Smith v. Ortho Pharm. Corp., 770 F. Supp. 1561, 1565 (N.D. Ga. 1991). "Perhaps in the world of medicine nothing is absolutely certain. Nevertheless, . . . it is the intent of our law that if the plaintiff's medical expert cannot form an opinion with sufficient certainty so as to make a medical judgment, there is nothing on the record with which a jury can make a decision with sufficient certainty so as to make a legal judgment." Zwiren v. Thompson, 276 Ga. 498, 501 (2003) (affirming jury verdict in favor of defendants).

Plaintiffs have to show both "general" and "specific" causation. General causation is the capacity of a product to cause an identified injury. Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1357 (N.D. Ga. 1999) (granting summary judgment for medical device manufacturer). Specific causation is proof that the

product in question caused the injury of which the plaintiff complains. Id.

Plaintiffs cannot prove either here.

Plaintiffs are apparently proffering a heretofore unproven, speculative theory that Ms. Lakey is suffering from the effects of “toxic mold biotoxin,” whatever that may mean. This novel assertion, concocted by Dr. Kolb – a self-proclaimed psychic and holistic healer – is untested, not peer reviewed, and not generally accepted. Without question, plaintiffs’ counsel was correct to acknowledge the “analytical gap” and “missing link” in plaintiffs’ causation theory.

Plaintiffs’ lack of any causation proof is coupled with affirmative uncontested evidence showing that there is no link between plaintiffs’ alleged injuries and the Mentor implants. The Mentor implants were manufactured according to specifications and underwent pre-shipment quality assurance and sterility testing and inspection. (SOF ¶¶ 9-20). Before implantation, plaintiffs’ physician confirmed that the implants were sterile and lacked any defects or anomalies. (SOF ¶ 25). And, when they were removed, the implants had not malfunctioned and did not appear to contain any foreign material. (SOF ¶¶ 27-31).

These undisputed facts are bolstered by testimony from plaintiffs’ own experts. For instance, Dr. Kolb testified that she believes Ms. Lakey’s injuries

were caused by toxic mold biotoxin, not directly by the Mentor implants.² (SOF ¶ 41). And both of plaintiffs' experts, Dr. Kolb and Dr. Blais, agree that any exposure to toxic mold would have been due to external contamination of the implants or environmental exposure – not any defect in the implants themselves. (SOF ¶¶ 41, 60-61, 68).

At bottom, plaintiffs have not shown support for any of the numerous underlying suppositions that would have to exist to prove their causation theory. For example, plaintiffs have not demonstrated that there actually is mold in the Mentor implants. Plaintiffs have not demonstrated that any such mold is "toxic" or harmful. Plaintiffs have not demonstrated that any material in her left implant was capable of producing, and actually did produce, biotoxins. Plaintiffs have not proven that any biotoxins could leak out of the implant into plaintiff's body. Plaintiffs have not shown that there was enough biotoxin to cause her injuries. And, perhaps most importantly, plaintiffs have not proffered evidence that biotoxins are capable of causing the type of symptoms plaintiff alleges (general causation) or that biotoxins in fact caused Ms. Lakey's injuries in this case (specific causation). (SOF ¶¶ 34-39, 51-57, 67-68, 70).

² Plaintiff's other expert, Pierre Blais, stated that he was not providing testimony on causation. (SOF ¶ 72).

Moreover, plaintiffs have not ruled out other potential sources of the alleged injuries. Ms. Lakey is apparently allergic to mold; she may have been exposed to mold in her residence or workplace. Ms. Lakey may have had an infection due to bacteria naturally occurring in her body or on her skin unrelated to her implants. And it is undisputed that Ms. Lakey was diagnosed with, and treated for, systemic candidiasis, a serious fungal infection unrelated to her implants. (SOF ¶ 33). Ms. Lakey was also being treated for severe anxiety and Obsessive-Compulsive Disorder, likely the cause of her palpitations and some of her other symptoms. (SOF ¶ 69). None of these possible alternative causes have been ruled out through plaintiffs' expert testimony.

Given that plaintiffs utterly have no support for their causation theory and, indeed, that the undisputed facts confirm that it is unfounded, summary judgment for Mentor is appropriate.

II. PLAINTIFFS' NEGLIGENCE CLAIMS FAIL AS A MATTER OF LAW BECAUSE PLAINTIFFS HAVE NO PROOF MENTOR BREACHED ANY DUTY.

Notwithstanding that plaintiffs can prove neither a product defect nor proximate causation, their negligence claim fails also because plaintiffs cannot show that Mentor fell below the appropriate standard of care. This, too, is another reason summary judgment is appropriate.

Georgia law is clear that “[n]egligence is not to be presumed, but is a matter for affirmative proof.” Collins v. Ralston & Ogletree, Inc., 186 Ga. App. 583, 584 (1988). In the absence of affirmative proof of negligence, the Court must conclude that Mentor performed its duty and was free from negligence. Id. Plaintiffs must prove each of four elements of a negligence claim: duty, breach of duty, proximate causation, and injury. Wessner, 250 Ga. at 200. Expert testimony is required to establish the appropriate standard of care where the conduct at issue is beyond the knowledge of the average layperson. Bilt Rite of Augusta, Inc. v. Gardner, 221 Ga. App. 817 (1996) (standard of care must be proven by expert testimony because a jury cannot rationally apply negligence principles without evidence of what a reasonable defendant would have done under similar circumstances); Johnson v. DOT, 245 Ga. App. 839 (2000) (expert testimony required to establish the proper standard of care regarding highway maintenance).

As an initial matter, plaintiffs have no proof whatsoever – expert or otherwise – that Mentor breached a duty to plaintiffs or fell below the standard of care. Without this basic, fundamental proof, plaintiffs’ negligence claim should be dismissed out of hand. And what’s more, the undisputed facts on record confirm that Mentor acted reasonably in designing and manufacturing plaintiffs’ implants

and in warning plaintiff's physician regarding the risks associated with the implants.

A. Mentor Used Reasonable Care in Manufacturing Plaintiff's Implants.

Even if plaintiffs could prove a product defect (which they cannot), that does not mean that Mentor was negligent See, e.g., Home Ins. Co. v. Caterpillar, Inc., 202 Ga. App. 522, 523 (1992) (affirming summary judgment for manufacturer); United States Fidelity & Guaranty Co. v. J.I. Case Co., 209 Ga. App. 61, 64 (1993) (affirming grant of j.n.o.v. in favor of manufacturer); Owens v. General Motors Corp., 272 Ga. App. 842, 848 (2005) (affirming summary judgment on negligence claim).

For example, in Williams v. American Medical Systems, the plaintiff alleged that the tubing of his penile implant had become disconnected, causing an infection. Even though there was evidence of a product defect, the court affirmed summary judgment on the plaintiff's negligence claim. The court found that because AMS submitted uncontroverted evidence that every implant made was subjected to inspection, functional testing and sterilization, and the plaintiff produced no evidence of negligent manufacture, summary judgment was proper. Id. at 683. "While the evidence here may have been sufficient to establish that an inherent defect in the penile implant caused it to separate, which is enough to prove

a strict liability claim, it was not demonstrated that the defect was the result of any negligence by [the manufacturer].” Williams, 248 Ga. App. at 684 (emphasis supplied).

Here, the undisputed evidence confirms that plaintiffs’ implants were manufactured properly. Mentor followed FDA good manufacturing practices and used reasonable care in the manufacturing process. (SOF ¶¶ 9-20, 24). The implants conformed to their design specifications and were rigorously tested and inspected. (SOF ¶¶ 9-20, 24). There is no evidence to the contrary.

B. Mentor Used Reasonable Care in Designing Plaintiff’s Implants.

Plaintiffs have submitted no evidence that Mentor negligently designed its implants. The undisputed facts show that implant design was sound.

Georgia courts typically employ a risk/utility test in considering a product’s design regardless of whether the claim is brought in negligence or strict liability. Banks v. ICI Am., Inc., 264 Ga. 732, 735 (1994). The risk/utility test incorporates the concept of “reasonableness” and asks “whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk posed by the design, the usefulness of the product in that condition, and the burden on the manufacturer to take the necessary steps to eliminate the risk.” Id. at 734. The court should evaluate a non-exhaustive list of

factors in analyzing the risk/utility balancing test.³ A manufacturer's compliance with federal regulations regarding the design of a product is a factor demonstrating that the manufacturer acted reasonably. Id. at 736 n.6.

The record evidence here confirms that the benefits of Mentor's saline-filled breast implants outweigh the risks. Plaintiff's plastic surgeon, Dr. Pound, testified that he only prescribes Mentor's saline breast implants when the benefits outweigh the risks. (SOF ¶ 64). In his opinion, the benefits of saline-filled breast implants outweighed the risks in plaintiff's specific case. (SOF ¶ 64). Moreover, the FDA, in approving Mentor's PMA application for its saline-filled breast implants, expressly found that the implants were safe and effective and that the benefits outweigh the risks. (SOF ¶ 4). Thus, to the extent plaintiffs assert a negligent design claim, it, too, fails as a matter of law.

³ These factors include: the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, *i.e.*, the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the state of the art at the time the product is manufactured; the ability to eliminate danger with a feasible alternative design without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product's price or by purchasing insurance. Banks, 265 Ga. at 736 n.6.

C. Mentor Used Reasonable Care in Its Warnings.

It is undisputed that Mentor adequately warned plaintiff's physician of the inherent, known risks associated with its implants. There is no evidence suggesting otherwise.

Georgia has adopted the learned intermediary doctrine. Under that doctrine, "the manufacturer of a prescription drug or medical device does not have a duty to the patient to warn of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." McCombs v. Synthes (U.S.A.), 277 Ga. 252 (2003), remanded to 266 Ga. App. 304 (2004) (affirming summary judgment for manufacturer on learned intermediary doctrine).⁴ The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the "decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities."

⁴ See also Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1279-81 (11th Cir. 2002) (affirming summary judgment for manufacturer applying Georgia law); Presto v. Sandoz Pharms. Corp., 226 Ga. App. 547, 548-49 (1997) (affirming summary judgment for manufacturer); Williams v. Am. Med. Sys., 248 Ga. App. 682, 685 (2001) (affirming summary judgment for manufacturer on failure to warn claim); Lance v. Am. Edwards Labs., 215 Ga. App. 713, 716 (1994) (affirming summary judgment for manufacturer).

McCombes, 277 Ga. at 252 (quoting Lance, 215 Ga. App. at 716). Thus, the proper inquiry here is whether Mentor adequately warned Dr. Pound of the foreseeable risks associated with the implants.

Plaintiffs have no expert testimony suggesting that Mentor's warnings to Dr. Pound were inadequate. In fact, it is undisputed that Mentor adequately warned Dr. Pound about the known potential risks associated with the saline breast implants in its FDA-approved Product Insert Data Sheet ("PIDS"), which accompanied every set of saline breast implants Mentor sold. (SOF ¶¶ 3-8). Dr. Pound himself agreed that Mentor properly warned him of the risks associated with saline-breast implants. (SOF ¶ 65). To the extent plaintiff claims she suffered from an infection, Mentor's PIDS warns of that risk and it is undisputed that plaintiff actually was warned of the risk of infection by Dr. Pound. (SOF ¶¶ 3-8, 23). Both plaintiff and her physician were well-warned. Like plaintiffs' other negligence claims, the negligent failure to warn claim must be dismissed.

III. PLAINTIFFS' INTENTIONAL INFILCTION OF EMOTIONAL DISTRESS CLAIM FAILS.

Aside from the lack of product defect and causation, plaintiffs' intentional infliction of emotional distress claim fails for other reasons, too. Under Georgia law, plaintiffs must present evidence that: (1) Mentor's conduct was intentional or reckless; (2) Mentor's conduct was extreme and outrageous; (3) there was a causal

connection between the wrongful conduct and the emotional distress; and (4) the emotional distress was severe. Ruotanen, 246 Ga. App. at 435. “Whether a claim rises to the requisite level of outrageousness and egregiousness to sustain a claim for intentional infliction of emotional distress is a question of law.” Id.

“It is not enough if a defendant acts with intent that is tortious or even criminal, or that he has intended to inflict emotional distress, or even if his conduct was characterized by malice entitling the plaintiff to punitive damages. Liability has been found only where the conduct has been so outrageous in character and extreme in degree as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community.” Id.

(quoting Restatement (Second) Torts § 46 at 72-73 (comment d)). Generally, in such a case the recitation of the facts to an average person would arouse his resentment against the actor and lead him to exclaim, “Outrageous!” Comsouth Teleservs., Inc. v. Liggett, 243 Ga. App. 446, 448 (2000).

There is no evidence – nor could there ever be – that Mentor engaged in outrageous and egregious intentional conduct causing plaintiff severe emotional distress. Mentor’s implants were designed and manufactured according to stringent specifications and FDA oversight. The implants were removed intact and did not leak or malfunction. And they caused plaintiffs no injury. There is no

evidence even approaching *negligence* in this case, let alone outrageous misconduct. Not surprisingly, even Ms. Lakey agrees that Mentor did not intentionally try to harm her. (SOF ¶ 71). Based on the undisputed facts, summary judgment on this claim is proper.

IV. PLAINTIFFS' PUNITIVE DAMAGES CLAIM FAILS.

Plaintiffs' claim for punitive damages under O.C.G.A. § 51-12-5.1, which is derivative of their two tort claims, must also fail. According to the statute, "Punitive damages may be awarded only in such actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that the entire want of care which would raise the presumption of conscious indifference to consequences."

Where a manufacturer complies with federal regulations in the design, manufacturing and warnings associated with its product, punitive damages are not available. "[P]unitive damages, the purpose of which is to 'punish, penalize or deter,' are, as a general rule, improper where a defendant has adhered to [applicable federal] regulations." Stone Man, Inc. v. Green, 263 Ga. 470, 472 (1993) (reversing award of punitive damages). See also Welch v. General Motors Corp., 949 F. Supp. 843, 844-45 (N.D. Ga. 1996) (granting summary judgment on plaintiff's punitive damages claim). That is because compliance with federal

regulations tends to show that there is no clear and convincing evidence of the type of willful misconduct, malice, fraud, oppression or conscious indifference to support an award of punitive damages. Stone Man, 263 Ga. at 472; Barger v. Garden Way, Inc., 231 Ga. App. 723, 728 (1998).

Mentor has submitted undisputed evidence that it complied with all federal regulations in designing, manufacturing and warning about its implants. (SOF ¶¶ 2-17). There is no evidence whatsoever – let alone clear and convincing evidence – that would justify punitive damages in this case. Regardless of the Court’s ruling on plaintiffs’ negligence and emotional distress claims, the punitive damage claim should be dismissed.

V. PLAINTIFF’S HUSBAND’S LOSS OF CONSORTIUM CLAIM IS DERIVATIVE AND ALSO FAILS.

To the extent plaintiff’s husband is bringing a loss of consortium claim⁵ – none is pleaded in the complaint – it is derivative of plaintiff’s other claims. See Supchak v. Pruitt, 232 Ga. App. 680, 684 (1998). As plaintiff’s claims fail, so, too, must his loss of consortium claim. Id.

⁵ Mr. Lakey would not have standing to assert any of the other claims in the First Amended Complaint.

CONCLUSION

For all of the foregoing independent reasons, summary judgment should be granted for Mentor.

Dated: August 22, 2006

Respectfully submitted,

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LOCAL RULE 7.1(D) CERTIFICATION

Pursuant to Local Rule 7.1(D), I hereby certify that this brief has been prepared with Times New Roman, 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that, on August 22, 2006, I electronically filed Defendant Mentor Corporation's Motion for Summary Judgment and Memorandum in Support using the CM/ECF system which will automatically send email notification of such filing to the following attorneys of record:

Frances L. Spinelli
Roger C. Wilson

Respectfully submitted this 22nd day of August, 2006.

/s/ Dustin B. Rawlin

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